



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/544,154

08/01/2005

Francis X. Smith

3009099 US01

6432

44331 7590 06/09/2009

HISCOCK & BARCLAY, LLP
2000 HSBC PLAZA
100 Chestnut Street
ROCHESTER, NY 14604-2404

EXAMINER

BASQUILL, SEAN M

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

06/09/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/544,154	Applicant(s) SMITH, FRANCIS X.	
	Examiner Sean Basquill	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1612

DETAILED ACTION

Applicants are advised, in future correspondence with the office, to reflect the change of examiners from TRISTAN MAHYERA to SEAN BASQUILL.

Status of the Claims

1. New Claims 3-20 have been added, resulting in Claims 1-20 being presented for examination.

Previous Rejections

2. Applicants' arguments, filed 31 March 2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1-3 and 5-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,817,277 (hereinafter "Mowrey-McKee"), in view of U.S. Patent 5,741,817 (hereinafter "Chowhan").

Mowrey-McKee describes methods and compositions for the disinfection of contact lenses. (Abs.). The compositions to be used in the method of disinfecting contain tromethamine,

Art Unit: 1612

or TRIS, in a concentration of between 0.5-1.2% (C.4-9, Examples 1A, 1B, 2a-i, 3C, 4, and 5), microbicides such as hydrogen peroxide in concentrations ranging between 50-200 ppm (0.005-0.02%) or PHMB in concentrations such as 0.0001% (1 ppm) (C.3, L.5-9; C.7-8, Examples 3C & 4), chelating agents such as EDTA (C.2, L.36-59), buffered to a pH of between 6-8, preferably 6.8-7.8 or 7.3-7.7 (C.2, L.60-67), tonicity adjusters to adjust the composition's osmolality to approximately 240-310 mOsm/kg (C.3, L.20-32), such as sodium chloride in concentrations ranging between 0.3-0.44% (C.4-8, Examples 1A, 1B, 3C, 4, and 5), and surfactants in concentrations ranging between 0.0001-20%, preferably 0.005-5%, more preferably between 0.025-1% (C.3, L.33-47).

Mowrey-McKee does not describe including L-histidine in the composition, nor is a single specific embodiment encompassing all of the above components in the above referenced quantities described.

That being said, however, it must be remembered that “[w]hen a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious.” *KSR v. Teleflex*, 127 S.Ct. 1727, 1740 (2007) (quoting *Sakraida v. A.G. Pro*, 425 U.S. 273, 282 (1976)). “[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious”, the relevant question is “whether the improvement is more than the predictable use of prior art elements according to their established functions.” (*Id.*). Addressing the issue of obviousness, the Supreme Court noted that the analysis under 35 USC 103 “need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would

Art Unit: 1612

employ.” *KSR v. Teleflex*, 127 S.Ct. 1727, 1741 (2007). The Court emphasized that “[a] person of ordinary skill is... a person of ordinary creativity, not an automaton.” *Id.* at 1742.

Consistent with this reasoning, it would have obvious to have selected various combinations of the disclosed TRIS buffer, microbicides including PHMB and hydrogen peroxide, EDTA, sodium chloride, and surfactants in the quantities described above from within the disclosure of Mowrey-McKee, to arrive at the instantly claimed ophthalmic compositions, aside from the histidine component of the instant claims, “yielding no more than one would expect from such an arrangement.”

Concerning the claimed ranges of components of the instant application, while the prior art does not disclose the exact claimed values, the ranges of the claimed composition components described in Mowrey-McKee overlap with or touch upon those of the instant claims. In such instances even a slight overlap in range establishes a *prima facie* case of obviousness. *In re Peterson*, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003).

Chowhan describes the use of low molecular weight amino acids in ophthalmic compositions to increase the efficacy of antimicrobial preservatives, especially when used for the rinsing and storage of contact lenses. (Abs.; C.1, L.45-60). The useful amino acids therein described include histidine, which Chowhan indicates may be used in concentrations ranging from about 0.01-7%. (C.2, L.1-20).

It would have been *prima facie* obvious to one having ordinary skill in the art to have incorporated the preservative enhancing amino acids including histidine of Chowhan into the ophthalmic compositions of Mowrey-McKee. One having ordinary skill in the art at the time of the instant invention would have been motivated to do so because of the explicit teaching of

Art Unit: 1612

Chowhan that the inclusion of low molecular weight amino acids improves the efficacy of antimicrobial preservatives in ophthalmic solutions, particularly those used for the rinsing and storage of contact lenses. Generally, it is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for same purpose, in order to form a third composition to be used for the very same purpose. The idea for combining them flows logically from their having been individually taught in the prior art. MPEP 2144.06.

4. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mowrey-McKee as modified by Chowhan as applied to claims 1-3 and 5-20 above, and further in view of U.S. Patent 5,620,970 (hereinafter “Han”).

Mowrey-McKee as modified by Chowhan describes compositions and methods of disinfecting contact lenses as detailed above, but does not specifically describe hydroxyethoxylated castor oil among the surfactants which may be used in the composition and methods as claimed.

Han indicates that polyethoxylated castor oils such as CREMPHOR EL are known to be useful as surfactants in topical ophthalmic compositions. (C.2, L.1-15).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time of the instant invention to have substituted the surfactant CREMOPHOR EL of Han for the surfactants of Mowrey-McKee as modified by Chowhan to provide a topical ophthalmic solution for the disinfection of contact lenses. One having ordinary skill in the art at the time of the instant invention would have been motivated to do so because they would have recognized that the CREMOPHOR ophthalmic surfactant of Han was a suitable replacement for, or equivalent

Art Unit: 1612

of, the ophthalmic surfactants of Mowrey-McKee as modified by Chowhan. Generally, it is *prima facie* obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended use. MPEP 2144.07. Additionally, it is *prima facie* obvious to substitute one equivalent component for another, each of which is taught by the prior art to be useful for same purpose, in order to form a third composition to be used for the very same purpose. The idea for combining them flows logically from their having been individually taught in the prior art. MPEP 2144.06.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

Art Unit: 1612

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-14, 16, 18-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2, 4, 7, 8, and 10-19 of copending Application No. 11/613,061. Although the conflicting claims are not identical, they are not patentably distinct from each other because the genera described in the '061 application overlap with the genera claimed in the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. Claims 1-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 7-13 of copending Application No. 10/544,149 in view of U.S. Patent 5,741,817 ("Chowhan").

Art Unit: 1612

Claims 1-5 and 7-13 of the '149 application describe ophthalmic solutions comprising hydrogen peroxide, cationic polymeric preservatives, buffers, surfactants, germicides, and chelating agents as put forth in the instant claims, but does not include L-histidine.

Chowhan describes the use of low molecular weight amino acids in ophthalmic compositions to increase the efficacy of antimicrobial preservatives, especially when used for the rinsing and storage of contact lenses. (Abs.; C.1, L.45-60). The useful amino acids therein described include histidine, which Chowhan indicates may be used in concentrations ranging from about 0.01-7%. (C.2, L.1-20).

It would have been *prima facie* obvious to one having ordinary skill in the art to have incorporated the preservative enhancing amino acids including histidine of Chowhan into the ophthalmic compositions of the '149 application. One having ordinary skill in the art at the time of the instant invention would have been motivated to do so because of the explicit teaching of Chowhan that the inclusion of low molecular weight amino acids improves the efficacy of antimicrobial preservatives in ophthalmic solutions, particularly those used for the rinsing and storage of contact lenses. Generally, it is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for same purpose, in order to form a third composition to be used for the very same purpose. The idea for combining them flows logically from their having been individually taught in the prior art. MPEP 2144.06.

This is a provisional obviousness-type double patenting rejection.

Art Unit: 1612

7. Claims 1, 3-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 and 8 of copending Application No. 11/613,050 in view of U.S. Patent 5,741,817 ("Chowhan").

Claims 1-5 and 8 of the '050 application describe ophthalmic compositions comprising hydrogen peroxide producing agents, cationic polymeric preservatives, buffers and surfactants of the instant invention, but does not specify the inclusion of L-histidine.

Chowhan describes the use of low molecular weight amino acids in ophthalmic compositions to increase the efficacy of antimicrobial preservatives, especially when used for the rinsing and storage of contact lenses. (Abs.; C.1, L.45-60). The useful amino acids therein described include histidine, which Chowhan indicates may be used in concentrations ranging from about 0.01-7%. (C.2, L.1-20).

It would have been *prima facie* obvious to one having ordinary skill in the art to have incorporated the preservative enhancing amino acids including histidine of Chowhan into the ophthalmic compositions of the '050 application. One having ordinary skill in the art at the time of the instant invention would have been motivated to do so because of the explicit teaching of Chowhan that the inclusion of low molecular weight amino acids improves the efficacy of antimicrobial preservatives in ophthalmic solutions, particularly those used for the rinsing and storage of contact lenses. Generally, it is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for same purpose, in order to form a third composition to be used for the very same purpose. The idea for combining them flows logically from their having been individually taught in the prior art. MPEP 2144.06.

This is a provisional obviousness-type double patenting rejection.

Conclusion

No Claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean Basquill whose telephone number is (571) 270-5862. The examiner can normally be reached on Monday through Thursday, between 8AM and 6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sean Basquill
Art Unit 1612

/Brandon J Fetterolf/

Primary Examiner, Art Unit 1642